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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,072	01/15/2002	Anthony J. Sinskey	1533.0790002	3733
26111	7590	04/05/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			MONSHIPOURI, MARYAM	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,072	SINSKEY ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 15-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/29/02</u> . | 6) <input type="checkbox"/> Other: ____. |

Applicant's response to restriction requirement filed 3/8/2004 is acknowledged.
Applicant elected Group II invention, drawn to claims 15-17 without traverse. Claim 14 is withdrawn as drawn to non-elected invention.

DETAILED ACTION

Claims 15-17 are under examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The step of producing the amino acids. Instant claim 15 and its dependent claims 16-17 are unclear because the recited steps are identical to those used for expression of recombinant pyruvate carboxylase. No step connecting the use of said enzyme in amino acid production is recited.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using SEQ ID NO:2 and recited homologs thereof for production of lysine in transformed, fermented *Corynebacterium glutamicum*, does not reasonably provide enablement for making any amino acid using

said enzyme and homologs thereof. Claim 15 as recited is directed to all methods of preparation of amino acids both in whole cells (bacteria etc.) and in vitro, which utilize SEQ ID NO:2 and its claimed homologs, while claim 16, having a smaller scope, is directed to all methods of preparation of lysine both in whole cells and in vitro, which utilize pyruvate carboxylase (SEQ ID NO:2) and its claimed homologs.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach about all possible amino acids which may be made by claimed pyruvate carboxylase and homologs thereof both in vitro and in a whole cell and the steps which should be followed in order to arrive at such amino acids. No examples of any amino acids beyond lysine and method of its production in fermented, transformed, *Corynebacterium glutamicum* is provided either. Current state of prior art is unpredictable about how to use SEQ ID NO:2 and homologs thereof in production of any amino acid because pyruvate carboxylase is involved in many biochemical pathways leading to the production of many amino acids, under variety of conditions both in vitro and in a whole cell.

Therefore due to lack of sufficient teachings and examples about steps and conditions, hosts (bacteria etc.) used for making each amino acid one of skill in the art has to go through the burden of undue experimentation in order to use said enzyme and

homologs thereof in both in vitro and in a whole cell production of each amino acid and as such the claims go beyond the scope of the disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters-Wendisch et al. (Microbiology 143, 1095-1103, 4/1997, cited in the IDS). Peters-Wendish teaches about *Corynebacterium glutamicum* bacteria (*C. glutamicum*), including the lysine producer (see page 1096) species which produces even more lysine than the Wild type *C. glutamicum*, and their growth on minimal media containing lactate, and observes PCx activity by its linear dependence on cell concentration, incubation time etc. (see page 1097 second column). Since *C. glutamicum* inherently produces lysine, under growth conditions indicated above, and comprises PCx, that is at least 95% identical to SEQ ID NO:2 by inherency because it originates from the same source as SEQ ID NO:2 of this invention, Peters-Wendish teaches a method of producing lysine using PCx of this invention, anticipating claims 15-16.

No claims are allowed.

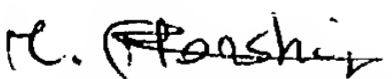
Note:

A method of making lysine by fermenting *C. glutamicum* comprising recited homologs of SEQ ID NO:2 with PCx activity such that PCX is expressed 2-20 fold higher than wild type *C. glutamicum* is free of prior art. Further, the prior art does not teach or suggest such specific method, rendering it also non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maryam Monshipouri Ph.D.

Primary Examiner